



THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

MAY 29 2002

RECEIVED

#111C
6-6-02

In re Application of: Eberhard Nieschlag et al.

Serial No.: 09/764,149

Group Art Unit: 1615

Filed: January 19, 2001

Examiner:
Rachel M. Bennett

For: MALE CONTRACEPTIVE FORMULATION COMPRISING NORETHISTERONE

SUPPLEMENTAL AMENDMENT

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

Supplemental to the Amendment filed May 21, 2002, kindly amend the above-identified application as follows.

IN THE SPECIFICATION

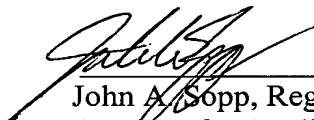
Replace page 20, in its entirety, with the attached new page 20. A marked up version is not supplied since no changes are made to the page, it is merely being replaced by a more legible copy.

REMARKS

A substitute, more legible, page 20 is being submitted per the Examiner's request in the Office Action of December 21, 2002.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



John A. Sopp, Reg. No. 33,103
Attorney for Applicants
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Boulevard, Suite 1400
Arlington, VA 22201
Direct Dial: 703-812-5315
Facsimile: 703-243-6410
Email: sopp@mwzb.com

FILED: May 28, 2002

Table 1

1.1.1 Study flow chart

Visit	Screening		Start	Treatment												Observation			
	1	2		3	4	5	6	7	8	9	10	11	12	13	14	15	16		
Assessment	A	B ¹	day 0 ²	W2 ³	W4	W6	W8	W12	W16	W18	W20	W24	W28	W36	W44	W56			
Group A																			
NET-EN administration (mg)			200			200			200		200								
TU administration (mg)				1000		1000			1000		1000								
Group B																			
NET-EN administration (mg)			400			400			400		400								
TU administration (mg)			1000			1000			1000		1000								
Group C																			
NET-A administration (mg)			10 mg																
Dispensation of vials			V 1/2																
TU administration (mg)			1000						1000		1000								
Inform Consent/Demographics	ABC																		
Check of Inclusion/Exclusion	ABC		ABC																
Randomization/Diary dispensed			ABC																
Medical/androl/medication history	ABC	ABC	ABC																
Vital signs	ABC	ABC																	
Physical examination	ABC				ABC				ABC										
Andrological examination	ABC				ABC				ABC										
Semen analysis	ABC	ABC			ABC				ABC										
General laboratory	ABC																		
Hormones	ABC	ABC			A	ABC	ABC	ABC	ABC		ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
Exam/Ultrasonography of prostate		ABC							ABC										
Ultrasonography of testes		ABC							ABC										
Return of diary/vials, if available																			
AEs/concomitant medication				A	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
Questionnaire	ABC	ABC			ABC			ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC

¹ At least 7 days after visit 1² Not more than 8 weeks after visit 1³ A deviation of ± 5 days will be tolerated

10